Remarks:

Claims 4, 9, 11, 17, and 20-29 remain for consideration in this application, with claims 4, 17, 20, and 28 being in independent format. The claims of group 2 (claims 12-15) were previously withdrawn pursuant to the restriction requirement. Claims 20-29 are new. No new matter has been entered in this amendment.

Prior to addressing the Office Action in detail, Applicants note that the present invention solved a problem in the prior art. Specifically, as set forth on page 7 of the Specification, the *F. Necrophorum* leuokotoxin is large and highly unstable. Such characteristics render the leukotoxin difficult to work with. In order to overcome these problems, Applicants truncated the full length gene, and expressed truncated forms of the leukotoxin protein. All truncations were at least 339 amino acids in length. The prior art was silent as to the potential effect any truncations, and such effects could not have been predicted. Fortunately, the truncated sequences possessed a variety of desirable characteristics.

In the Action, claims 1, 4, 5, 6, 9-11, and 16-18 were rejected under 35 U.S.C. 112, first and second paragraphs for lacking written description and enablement for sequences having at least 87% sequence homology to the claimed sequences. In response, Applicants submit herewith a copy of a declaration filed in the parent application to this application. This declaration, by an individual of skill in the art, addressed a similar rejection in the parent case and Applicants respectfully request its entry in this divisional application. Furthermore, this limitation only remains in claims 4, 9, 11, (by their recitation of claim 4 within the claims), 17 and 29. In each of these claims, the claims have been further amended to provide further features which serve to further define the claim. In claims 4, 9, and 11, the claims recite, either explicitly or implicitly by their reference to an earlier claim that claimed sequences are selected from the group consisting of SEQ ID No. 8, SEQ ID No. 9, SEQ ID No. 10, SEQ ID No. 11, SEQ ID No. 12, SEQ ID No. 13, SEQ ID No. 14, and combinations thereof, and the claims still further recite that the claimed nucleotide sequences encode polypeptides that induce anti-leukotoxin antibodies in a mammal when administered to said mammal. Claim 17 also includes the features regarding the specific SEQ ID Nos. referred to above and that the polypeptide encoded by said nucleotide sequences confer effective protective immunity against *F. Necrophorum*

in a mouse. New claim 29 includes the feature that the nucleotide sequence has at least 87% sequence homology with at least 1,017 contiguous nucleotides from SEQ ID No. 8. As the specification clearly sets forth specific examples of sequences falling under the features of these amended claims and the Declaration included herewith verifies that one of skill in the art would be able to practice the full scope of the claims, Applicants assert that these rejections have been overcome.

The remainder of the independent claims have had the homology limitation removed, and the claims have been amended to recite that the claimed nucleotide sequences encode amino acid sequences comprising at least 339 contiguous amino acids from SEQ ID No. 1, which Applicants note is the amino acid sequence expressed by SEQ ID No. 8. Thus, the written description requirement is met by the new independent claims, as the specification clearly sets forth several examples of precisely what is claimed, that is, nucleotide sequences that encode amino acid sequences having at least 339 contiguous amino acids from SEQ ID No. 1 and which further induce anti-leukotoxin antibodies after administration of such amino acid sequences to a mammal. For other examples of sequences that would fall under the scope of such claims, the skilled artisan can follow the direction and teachings of the present application, as well as the knowledge available in the art regarding amino acid sequences capable of inducing antibody responses in mammals. With such direction and knowledge, those of skill in the art would be able to generate such sequences without undue experimentation. Applicants note that "undue experimentation" does not require perfection in the outcome of any such experimentation, but rather that the experimentation not be "undue." Accordingly, Applicants assert that all rejections under 35 U.S.C. 112 have been overcome for the new claims as well as for the amended claims.

Claim 11 was rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,804,190 to Struck (Struck). This claim now requires at least 87% homology over a 1017 nucleotide length portion of a sequence selected from the group consisting of SEQ ID No. 8, SEQ ID No. 9, SEQ ID No. 10, SEQ ID No. 11, SEQ ID No. 12, SEQ ID No. 13, SEQ ID No. 14, and combinations thereof. Struck does not teach or suggest such a homologous region and therefore cannot be said to anticipate or even obviate the present claims. Additionally, this claim contains all of the features of claim 4.

namely that it is selected from the group consisting of sequences having at least 87% sequence homology with SEQ ID No. 8, SEQ ID No. 9, SEQ ID No. 10, SEQ ID No. 11, SEQ ID No. 12. SEQ ID No. 13, SEQ ID No. 14, and combinations thereof, and the claimed sequence encodes a polypeptide that induces anti-leukotoxin antibodies in a mammal when administered to said mammal. For all of these reasons, Applicants assert that this rejection has been overcome.

Finally, the Action contained a rejection of claims 1, 6, 16, and 18 for new matter, namely the recitation of the claimed sequences "having a length of at least 1017 nucleotides" or "having therein at least 339 contiguous amino acids." Claims 1, 6, 16, and 18 have been canceled in this amendment, and the claims replacing these claims all contain features similar to those that were contained in claim 18. Specifically, all of the independent claims related to these canceled claims require an isolated nucleotide sequence that encodes an amino acid sequence having at least 339 contiguous amino acids from SEQ ID No. 1. Support for amino acid sequences having at least 339 amino acids can be found throughout the specification. For example, the Summary at pages 8-9 describes the full length leukotoxin gene, as well as the truncations tested as a part of this invention. Applicants note that the sequence listing that accompanied this application sets forth each sequence tested and referred to in the application and that all of such sequences contain at least 339 amino acids. Example 2, under the heading "Creation of Gene Truncations" reflects the enablement of and support for amplification of overlapping regions of the leukotoxin gene ranging in size from 1.1kb to 2.8 kb. Example 2 also contains a heading "Creation of Truncated Leukotoxin Polypeptides and Characteristics of Polyclonal Antisera Raised Against Them. Example 3 of this application provides still further support, as it too described truncating the full length leukotoxin gene and constructing smaller truncated forms of this sequence for PCR amplification for expression. Table 2 of Example 3 of the specification reflects the characterization of truncated forms of the nucleotide sequence of SEQ ID No. 1 as set forth in Claims 20 and 21, thereby further complying with the written description requirement. As noted in that Table, the truncated proteins ranged in size between 339 to 926 amino acids in length. Reference to the specification will show that each of these specific examples contains at least 336 contiguous amino acids from SEQ ID No. 1, which is the protein expressed by the nucleotide sequence of SEQ ID No. 8. Example 4 further sets forth the expression

of the truncated fragments of SEQ. ID No. 8 (again, which is the full length gene encoding SEQ ID No. 1), all of which are at least 339 amino acids in length. Finally, Example 9 sets forth even further support for the claimed invention, as each amino acid sequence tested has at least 339 contiguous amino acids from SEQ ID No. 1. Applicants note that this is consistent with the entire application. Thus, it cannot be said that the features related to amino acid or nucleotide sequence are not supported in the application as originally filed and Applicants respectfully request withdrawal of this rejection.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 50-2790.

Respectfully submitted,

By _____

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